Results. Humoral and CMI in the RZV group persisted through M13 appearing higher in the RZV group vs. placebo (Table 1). The frequency of solicited local AEs and of general AEs myalgia and fever was higher in the RZV group vs. placebo and balanced between study groups for the other general AEs, pIMDs and SAEs (including allograft rejections) (Table 2, Figure 1). No concerns regarding renal function were reported. Suspected HZ cases were recorded among 2 RZV and 6 placebo recipients. In the RZV group, within-participant pre- and post-vaccination solicited general AEs were reported at similar rates for fatigue, gastrointestinal symptoms and headache, and higher rates post-vaccination for myalgia, shivering, and fever (Figure 1).

Conclusion. RZV was highly immunogenic, eliciting robust humoral and CMI that persisted up to 12 months in adult renal transplant recipients. No safety concerns were identified over a 1-year follow-up.

Reference

1. de la Serna, BMT Tandem Meeting 2018, abs LBA2.

Funding: GlaxoSmithKline Biologicals SA

Table 1. Humoral and cellular immune responses at M2 and M13 (according-to-protocol cohort)

	RZV		Placebo		Adjusted ratio RZV:placebo
	N	Value	N	Value	
Humoral immune response (anti-gE antibody geometric mean concentration), mIU/mL (95% CI)					
Pre-vaccination	121	1354.4 (1118.3–1640.4)	119	1495.7 (1202.3–1860.8)	
Month 2	121	19163.8 (15041.5–24416.0)	119	1489.4 (1215.8–1824.7)	–
Month 13	111	8545.1 (6753.7–10811.5)	111	1572.7 (1269.6–1948.1)	–
Humoral vaccine response rate#, % (95% CI)					
Month 2	121	80.2 (**71.9**–86.9)	119	4.2 (1.4–9.5)	–
Month 13	111	66.7 (57.1–75.3)	109	6.4 (2.6–12.8)	–
Cell-mediated immune response (mean CD4⁺T-cell frequencies) (±SD)					
Pre-vaccination	31	110.9 (±182.1)	30	165.8 (±242.9)	–
Month 2	32	2433.1 (±2102.3)	31	157.0 (±274.8)	
Month 13	33	1320.9 (±1823.6)	31	129.4 (±197.9)	–
Cell-mediated immune vaccine response rate#, % (95% CI)*					
Month 2	28	71.4 (**51.3**–86.8)	28	0.0 (0.0–12.3)	–
Month 13	30	56.7 (37.4–74.5)	27	0.0 (0.0–12.8)	–
Adjusted humoral immune response (anti-gE antibody geometric mean concentration), mIU/ml (95% CI)**					
Month 2	121	19983.3 (15779.7–25306.7)	119	1427.3 (1310.0–1555.2)	14.0 (**10.9**–18.0) p <0.0001
Adjusted cell-mediated immune response (CD4⁺T-cell frequencies geometric mean), (95% CI)**					
Month 2	28	1440.5 (1044.4–1959.6)	28	83.5 (8.6–181.5)	17.3 (**5.9**–50.4) p <0.0001

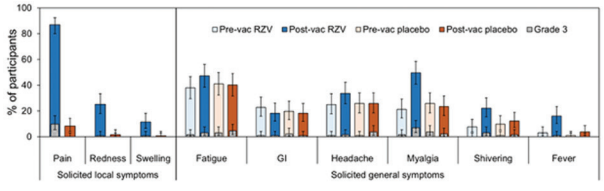
Month 2 & 13 (1 & 12 month[s] after last vaccination); N, number of participants with available results; CI, confidence interval; IU, international units. **Bolded values** indicate that success criteria were met for primary immunogenicity objective (lower limit of 95% CI ≥60% for humoral VRR) and secondary immunogenicity objectives (lower limit of 95% CI ≥50% for cell-mediated VRR, >3 for humoral GM ratio, and >1 for cell-mediated GM ratio).
*for the inferential analysis, the frequency of CD4⁺ T cells producing ≥2 activation markers from among IFN-γ, IL2, TNFα, and CD40 Ligand per 10^6 CD4⁺ T cells; **adjusted for baseline values. #Vaccine responses: (i) for humoral immune response: (a) in initially seronegative participants, a post-vaccination antibody concentrations ≥4-fold the cut-off for anti-glycoprotein E (gE) (4x97 mIU/ml); (b) in initially seropositive participants, a post-vaccination antibody concentration ≥4-fold the pre-vaccination antibody concentration; (ii) for cell-mediated immune response: (a) in participants with initial pre-vaccination T-cell frequencies below the cut-off ($320/10^6$ CD4⁺ T cells), a post-vaccination T-cell frequencies ≥2-fold the cut-off ($2x320/10^6$ CD4⁺ T cells); (b) in participants with initial pre-vaccination T-cell frequencies above the cut-off, a post-vaccination T-cell frequencies ≥2-fold the pre-vaccination T-cell frequencies.

Table 2. Incidence of unsolicited AEs, SAEs, pIMDs and suspected HZ cases (TVC, overall/participant)

AEs			n (%) RZV N=132	n (%) Placebo N=132	Reporting period
Unsolicited AEs	All	Any grade	9 (6.8%)	7 (5.3%)	7 days before first vaccination
		Grade 3	0 (0.0%)	0 (0.0%)	
	All	Any grade	51 (38.6%)	44 (33.3%)	30 days after each vaccination
		Grade 3	7 (5.3%)	5 (3.8%)	
	Related	Any grade	7 (5.3%)	3 (2.3%)	
		Grade 3	1 (0.8%)	0 (0.0%)	
	With medically attended visits		34 (25.8%)	29 (22.0%)	
SAEs	All		26 (19.7%)	33 (25.0%)	First vaccination up to study end
	Related		0 (0.0%)	1 (0.8%)	
	Fatal		1 (0.8%)	1 (0.8%)	
	Biopsy-confirmed allograft rejections		4 (3.0%)	7 (5.3%)	
pIMDs	All		4 (3.0%)	2 (1.5%)	
Suspected HZ cases	All (post 1 or 2 doses)		3 (2.3%)	7 (5.3%)	
	In participants post 2 doses		2 (1.5%)	6 (4.5%)	Second vaccination up to study end

TVC, total vaccinated cohort; AE, adverse event; n (%), number (percentage) of participants with at least one AE; SAE, serious AE; pIMD, potential immune-mediated disease; HZ, herpes zoster; N, number of participants with ≥1 one administered dose; grade 3, preventing normal activity; related, causally related to vaccination per investigator assessment.

Figure 1. Solicited local and general AEs reported within 7 days pre-vaccination and post each dose (TVC, overall/participant)



TVC, total vaccinated cohort; pre-vac, pre-vaccination adverse events (AEs); post-vac, post-vaccination AEs; GI, gastrointestinal symptoms (nausea, vomiting, diarrhea and/or abdominal pain); grade 3, preventing normal activity (for fatigue, GI, headache, myalgia, shivering), significant pain at rest and preventing normal everyday activities (for pain), having a surface diameter >100 mm (for injection site redness and swelling); for fever, oral temperature >39.0 °C was represented.

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2484. Pre-Transplant Vaccination Adherence in Pediatric Solid Organ Transplant Patients at a Large Academic Medical Center

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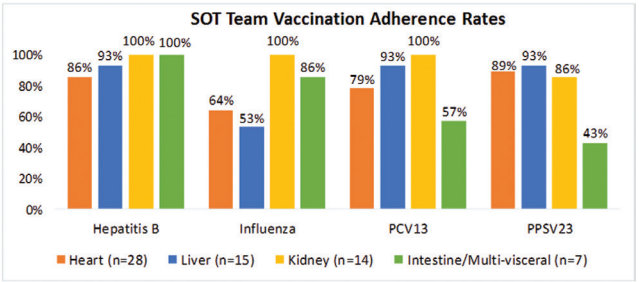
Background. Adherence rates for recommended pre-transplant (pre-txp) vaccinations in pediatric solid-organ transplant (SOT) patients are variable and practice-dependent. Cleveland Clinic Children's Hospital (CCCH) pre-txp adherence rates for select vaccines have not been described. The purpose of this study was to evaluate pre-txp adherence rates for the following vaccines: hepatitis B, influenza, pneumococcal conjugate (PCV13), pneumococcal polysaccharide (PPSV23), and hepatitis A (if at-risk).

Methods. This retrospective cohort study included patients undergoing initial pediatric heart, kidney, liver, or intestine/multi-visceral transplant at CCCH between 1/1/14 and 7/31/17. Data collected from the electronic medical record and Ohio Department of Health Statewide Immunization Information System included demographics, transplant-related data, immunization administration history, and quantitative/qualitative values for titer/serology. The primary objective of vaccination adherence rate was defined as the aggregate of patients who had completed the vaccine series, had positive titer/serology data, or were ineligible to receive the vaccine due to age or administration restrictions. Data are descriptive in nature and reported as number (percent) or median (interquartile range), as appropriate.

Results. 64 pediatric SOT recipients met inclusion criteria. Median age was 7.9 (2.1, 15.8) years. Majority of patients were American (73%) and male (63%). Most common organ was heart (41%), followed by liver (25%), kidney (21%), and intestine/multi-visceral (13%). Sixty-three (98%) patients underwent ID pre-txp evaluation. CCCH adherence rates were highest for hepatitis B at 92%, followed by PCV13 and PPSV23 at 84%, and influenza at 72%. Thirty-two (50%) patients were indicated to receive the hepatitis A vaccine and the respective adherence rate was 91%. Vaccination adherence by SOT team is described in Figure 1.

Conclusion. CCCH pre-txp vaccination adherence rates are higher than previously reported. Opportunities for improvement include influenza vaccination adherence across all SOT teams and PCV13/PPSV23 vaccination adherence in intestine/multi-visceral transplant patients.

Figure 1: CCCH SOT team vaccination adherence rates.



Disclosures. **All authors:** No reported disclosures.

2485. Circulating T Follicular Helper Cells and Immune Response Induced by Influenza Vaccine in Children With Acute Lymphoblastic Leukemia During Maintenance Therapy

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Background. Vaccine immune response is impaired in cancer patients. Follicular helper T lymphocytes (cTfh) are essential for high affinity and long lasting humoral response. The objective of this study was to evaluate the role of cTfh in the immune response induced by influenza vaccine in children with acute lymphoblastic leukemia (ALL).

Methods. Children with ALL in maintenance therapy and a control group of healthy children were included. Blood samples were taken on the day of vaccination (D0), and on day 28 (D28). The humoral response was evaluated by haemagglutination inhibition test and frequency of cTfh was studied by flow cytometry.

Results. Twenty-four children with ALL and 8 healthy children were included: 67 and 38% were women, median age of 5 years old in both groups. A 33% (8/24) of patients and 63% (5/8) of controls were seroprotected at D28. Seroprotected children at D28 were significantly older than non-protected ones (10 and 3.6 years respectively, P = 0,004). During follow-up, three children with ALL had influenza infection. An increase of percentage of cTfh cells from D0 to D28 was observed in both groups, but it was significant only in ALL patients (average for ALL, D0-D28: 18–23%, P = 0.003 and average for controls, D0-D28: 22–26%). No differences were found between seroprotected and non-seroprotected children in cTfh cell at D0 or D28. The increase of percentage of cTfh cells from D0 to D28 was observed in both groups, it was significant only in non-seroprotected subjects (average for seroprotected, D0-D28: 21–24% and average for non-seroprotected, D0-D28: 18–24%, P = 0.004).

Conclusion. Children with ALL achieved a lower seroprotection than healthy children. After vaccination, both groups had an increase of cTfh cells. We did not found an association between the percentage of cTfh cells and seroprotection at D28. The association between the lack of humoral response and cTfh dysfunction should be evaluated in further studies (We report public funding from Fondecyt grant Nº 11150970).

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2486. The Effectiveness of High-Dose Hepatitis B Vaccination in Patients Receiving Immunomodulatory Therapy

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Background. The course of hepatitis B virus (HBV) infection is more severe in patients using immunomodulatory drugs (ID) than in the normal population. This study evaluates the results of double-dose administration of HBV vaccine of 40 µg at months 0, 1, 2, and 6.

Methods. Anti-HBs negative patients presenting to our polyclinic between January 1 and July 1, 2017 and using ID were administered a double dose of HBV vaccine at months 0, 1, 2, and 6. Patients' primary diseases and comorbid factors were recorded. Anti-HBs titers above 10 mIU/mL 1 month after completion of vaccination schedules were regarded as response to vaccine.

Results. Eighty patients presented during the study. Seventeen patients failing to attend follow-ups were excluded. Twenty-eight (44.4%) of the 63 patients enrolled were men and 35(55.6%) were women. Patients' ages ranged between 18 and 66, with a mean age of 44.2 (±12.2) and a median value of 46. Comorbid factors were essential hypertension in 5 patients, diabetes mellitus in 4, and hypothyroid in 3. Vaccination was started within 2 weeks before commencement of ID or simultaneously with a biological agent in 29(46%) patients, and anti-HBs titers above 10 mIU/mL were achieved in 24 (82.8%). Thirty-four (54%) patients were started on vaccination while using medication [mean 21.1(±27.7) months], and anti-HBs titers above 10 mIU/mL were achieved in 29. Response was achieved in 53(84.1%) of all the patients in the study, while no response was obtained in 10 (15.9%). No gender difference was observed between the responding and non-responding patients. Response to vaccine was independent of sex, comorbid diseases, immunosuppressive agents, and time of commencement of vaccination (Table 1).

Table 1: Analysis of patients' vaccination responses

Vaccination response	Anti-HBs negative (n=10. 15.9%)	Anti-HBs positive (n=53. 84.1%)	
Mean age	47	43.8	
Male/female (%)	50/50	43.4/56.6	
Primary diseases	**n**	**n**	
Rheumatoid arthritis	5	11	
Ankylosing spondylitis	4	25	
Psoriasis	1	16	
Reactive arthritis	0	1	
Biological drug used	**n**	**n**	**n (%)**
Adalimumab	4	19	23 (36.5)
Infliximab	0	6	6 (9.5)
Etanercept	2	15	17 (27)
Golimumab	1	4	5 (7.9)
Tofacitinib	2	4	6 (9.5)
Abatasept	1	0	1 (1.6)
Ustekinumab	0	2	2 (3.2)
Tocilizumab	0	2	2 (3.2)
Certolizumab	0	1	1 (1.6)
Vaccination commenced prior to biological drug (%)	50	45.3	
Mean length of drug use among subjects using medication (months)	19.4 ±24.2	21.4 ±28.1	

Conclusion. In our study, anti-HBs positivity was achieved in 84.1% of patients receiving doses of 40 µg. Although the ideal situation is for patients to start receiving vaccination at least 2 weeks before starting ID, vaccination in the shortest time possible after commencement of treatment is recommended for previously unvaccinated patients. In conclusion, physicians need not be concerned that response to vaccination cannot be achieved in patients started on ID, and seronegative patients must be enrolled in the HBV vaccination program as quickly as possible.

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2487. Vaccination Rates in Post-Transplant Hematopoietic Stem Cell Transplant (HSCT) Patients: Where Do We Stand?

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Background. HSCT patients are at an increased risk of developing infections after transplant due to the loss of immunogenicity from prior vaccinations. Current national and international guidelines recommend routine revaccinations at a fixed dosing schedule for HSCT patients post-transplant. Although immunization adherence is vital to prevent infections, compliance with post-transplant vaccinations is unknown. The primary endpoint of this study was the completion rate of the post-transplant vaccination series. Secondary endpoints included identifying reasons for noncompliance, rates of breakthrough vaccine-preventable infections, and assessing post-vaccination antibody responses based on titers.

Methods. A single-center, retrospective study of adult HSCT patients at Yale New Haven Hospital between January 2010 and September 2015 was performed. Patients were excluded if: <18 years of age, deceased prior to one year post-transplant, transferred care to an outside facility, or were lost to follow-up.

Results. A total of 512 HSCT patients were evaluated. 390 (76%) patients were initiated on the vaccination series. Of the 390 patients, 275 (71%) patients were started at one year follow-up per institutional guidelines. The most common reasons for non-initiation or delayed initiation of the vaccine series included disease relapse (14%), active graft vs. host disease (9%), and the need for immunosuppressive therapy (5%). Of the patients initiated on the vaccination series, only 187 (48%) patients completed the entire vaccination series; with the majority of whom were autologous HSCT patients (72%). The most common reasons for an incomplete vaccination series included maintenance chemotherapy (19%), disease relapse (16%), and lost to follow-up (10%). Of the patients who completed the vaccination series, 19% had the appropriate post-vaccination titers obtained. Of the patients who received at least one or more doses of pneumococcal vaccine post-transplant, 8 patients (2%) developed a breakthrough infection with *S. pneumoniae*.

Conclusion. This study adds important data to the limited body of literature on HSCT vaccine compliance rates. Future studies on the best interventions to improve compliance rates are warranted.

Disclosures. **All authors:** No reported disclosures.

2488. The Impact of Reactogenicity After Administration of the Recombinant Zoster Vaccine Upon the Physical Functioning and Quality of Life of Older Adults

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